

REMARKS

Claims 10-22 and 24 are pending in this application.

All of the pending claims have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. Specifically, the claims have been rejected because the phrase "the target nucleic acid" in claims 10 and 11 has no antecedent basis. Applicants respectfully submit that this rejection has been obviated by the amendments set forth above to claims 10 and 11.

The claims also were rejected on the basis that in the phrase "a complementary sequence in an extension product of the primer corresponding to the target nucleic acid" the meaning of "corresponding" is unclear. Applicants submit that this rejection has been obviated by the amendments to claim 10 set forth above. Claim 12 also was found to be vague and indefinite because it is unclear whether the term "uncopied" means that the tail region is non-complementary to the template region. Applicants submit that this rejection has been obviated by the amendments to claims 10 and 11 and the cancellation of claim 12.

Claim 17 also was said to be vague and indefinite because it is unclear whether the integral signaling system is attached to the primer tail and then the integral signaling system is

released. Applicants respectfully submit that this rejection has been obviated by the amendment to claim 17 set forth above.

Claims 10-12 and 14-22 have been rejected under 35 U.S.C. § 102 as anticipated by PCT application WO 97/42345 by Whitcombe et al. (hereinafter referred to as the Whitcombe reference). The examiner asserted that Whitcombe discloses a diagnostic primer having a non-complementary tail comprising a tag and detector region. She described the tail as non-complementary to any relevant genomic sequence or adjacent region and asserted that the detector region can be detected by the use of fluorescence resonance energy transfer or by measuring a change in fluorescence polarization. She also asserted that the reference teaches that a solid phase probe can detect the immobilized primer extension products and that the primer comprises a restriction site on the middle position of the primer which can be cleaved releasing the detected fluorophore from its quencher. This rejection is traversed.

The Whitcombe reference does not teach or suggest the primers as defined in amended claims 10 and 11, nor does it teach or suggest primers which allow for the interactions defined in those claims. A key feature of the primers of the present invention is that the tail of the primer remains uncopied. In contrast, the invention of Whitcombe et al. will work only if a

copyable tail is used to provide the complement of the tag region for hybridization with the tag primer. This is clearly illustrated in figure 9 and subsequent figures in the Whitcombe reference. Each of these figures shows that the tail (tag region abc and detector region xyz) is copied.

Accordingly, the Whitcombe reference actually teaches away from a key feature of the primers of the present invention, the non-copyable tail portion. The Whitcombe reference thus does not anticipate the claimed invention.

Claims 13 and 24 have been rejected under 35 U.S.C. §103(a) as obvious over the Whitcombe reference in view of Mullis et al. The examiner applied the Whitcombe reference as she had in the preceding rejection but acknowledged that the reference does not teach that the primer has a blocking moiety or a kit containing the primer. The Mullis et al. reference was cited as disclosing an oligonucleotide having a deoxyribonucleotide or ribonucleotide blocking moiety as well as disclosing a kit containing primers. She asserted that one of ordinary skill in the art would have been motivated to make a primer containing a blocking moiety and a kit containing primers because of Mullis' discussion of them and because the use of primer kits was a common practice. This rejection is traversed.

The inadequacies of the primary, Whitcombe reference have been discussed above and that discussion is equally applicable to this rejection. Whitcombe teaches away from the primers of the present invention. The Mullis reference does not compensate for the deficiencies of the Whitcombe reference. The addition of a blocking moiety as taught by Mullis to the Whitcombe primers would not result in primers having the key features of the presently claimed primers and such primers would not work in the methods described in the application. The combination of the Whitcombe and Mullis references does not teach or suggest the primers or kits as set forth in the pending claims.

In view of the amendments and discussion set forth herein, Applicants respectfully submit that the presently claimed invention is in condition for allowance.

RESPECTFULLY SUBMITTED,					
NAME AND REG. NUMBER	Barbara G. Ernst, Reg. No.30,377				
SIGNATURE	<i>Barbara G. Ernst</i>			DATE	<i>Sept. 25, 2003</i>
Address	Rothwell, Figg, Ernst & Manbeck Suite 701-East, 555 13th Street, N.W.				
City	Washington	State	D.C.	Zip Code	20004
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031